UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

01/06/2000

MEMORANDUM

Subject: D259873
ACLD-128
EPA File Symbol 3377-LI

From: Wallace Powell, Biologist
Product Science Branch
Antimicrobials Division (7510C)

Thru: Karen P. Hicks, Team Leader
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Velma Noble, Product Manager, Team 31
Jacquie Campbell, Team Reviewer, Team 31
Regulatory Management Branch I
Antimicrobials Division (7510C)

BACKGROUND

The applicant, Albemarle Corporation, has submitted acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary dermal irritation, and dermal sensitization studies – MRID Nos. 449244-05 through 449244-09, respectively. The studies were submitted in support of product registration for ACLD-128, EPA File Symbol 3377-LI. The studies were initially reviewed for Product Science Branch (PSB) by Oak Ridge National Laboratory. The reviews are attached to this memorandum.

The applicant additionally has request a waiver of primary eye irritation data, based on corrosiveness indicated in the submitted primary dermal irritation study.

The active ingredients in the product are as follows:

| Active Ingredient | % by weight | EPA code |
|---|---|---|
| Didecyl dimethyl ammonium chloride ..... | 5.755 | 069149 |
| Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride ..... | 4.725 | 069105 |

## RECOMMENDATION

PSB concurs with the acute Toxicity Categories assigned by the attached study reviews. These Categories are listed in the table below and are applicable to all eight product formulations. The one "Basic" and seven "Alternative" formulations for the product appear substantially similar to each other, based on the submitted Confidential Statements of Formula.

| Data Requirement | Means of Support | Acute Toxicity Category |
|---|---|---|
| Acute Oral Toxicity | Submitted study, MRID 449244-05 | Category III, based on the calculated $LD_{50}$ |
| Acute Dermal Toxicity | Submitted study, MRID 449244-06 | Category III, based on the limit test |
| Acute Inhalation Toxicity | Submitted study, MRID 449244-07 | Category II, based on determination of a specific range for the $LC_{50}$ |
| Primary Eye Irritation | Waiver request | Category I, considered corrosive. Data waived, based on evidence of corrosion in submitted skin irritation study |
| Primary Dermal Irritation | Submitted study, MRID 449244-08 | Category I, with evidence of corrosion |
| Dermal Sensitization | Submitted study, MRID 449244-09 | Non-sensitizer |

## PRODUCT LABELING

Based on the above acute Toxicity Categories, the precautionary (human hazards) and first-aid statements on the submitted draft label (EPA Received date 09/17/99) are acceptable.

DATA EVALUATION REPORT

**ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE**
(ACLD-128)

STUDY TYPE: ACUTE ORAL TOXICITY - RAT (81-1)
MRID 44924405

Prepared for

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K129

Primary Reviewer:
Susan Chang, M.S.
Signature: S S Chang
Date: NOV 1 3 1999

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.
Signature: H.T Borges
Date: NOV 1 3 1999

Robert H. Ross, M.S., Group Leader
Signature: Robert H Ross
Date: NOV 1 3 1999

Quality Assurance:
LeeAnn Wilson, M.A.
Signature: L. A. Wilson
Date: NOV 1 3 1999

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

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Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

EPA Reviewer: Wallace Powell, ~~Ph.D.~~ _____, Date _____

EPA Work Assignment Manager: Nader Elkassabany, Ph.D. _____, Date _____

## DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat
OPPTS 870.1100 [§81-1]

DP BARCODE: D259873 SUBMISSION CODE: S569138
P.C. CODE: 069105 CASE NO.: 066315

TEST MATERIAL (PURITY): ACLD-128 (10.31% Quat, a.i.)

SYNONYMS: not reported

CITATION: Moore, G.E. (1999) Acute oral toxicity study in rats - Defined $LD_{50}$. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project identification number 7131, April 7, 1999. MRID 44924405. Unpublished.

SPONSOR: Albemarle® Corporation, Health & Environment, 451 Florida Street, Baton Rouge, LA 70801-1765

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 44924405) groups of five male and five female fasted young adult Sprague-Dawley derived rats were given a single oral 2000, 2700, or 3500 mg/kg dose of ACLD-128 (10.31% Quat, a.i., Lot No. 8504-117) and observed for 14 days.

Three male and five female high-dose rats, three male and two female mi-dose rats , and one male and one female low-dose rats died within five days of treatment. Hunched posture, anogenital staining, hypoactivity, diarrhea, reduced fecal volume, soft feces, and/or distended abdomens were noted from all rats. The survivors recovered by day 7. Some of the decedents had irregular respiration and gasping, were cold to touch, and/or exhibited prone posutre prior to death. All surviving rats had normal body weight gains. Moderately red lungs, red/yellow/black intestines, distended/fluid filled/moderately red stomachs, discolored livers, and gaseous distended gastrointestinal tract were noted from the decedents. No gross abnormalities were noted from the survivors.

**The oral $LD_{50}$s for males, females, and combined were 2801 mg/kg, 2572 mg/kg, and 2667 mg/kg, respectively.**

**ACLD-128 is in TOXICITY CATEGORY III based on the $LD_{50}$.**

This acute oral study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute oral study (81-1) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## I. MATERIALS AND METHODS

### A. MATERIALS

1. Test material: ACLD-128

   Description: blue liquid
   Lot/Batch #: 8504-117
   Purity: 10.31% a.i.
   Composition: 10.31% Quat

2. Vehicle and/or positive control

   None

3. Test animals

   Species: rat
   Strain: Sprague-Dawley derived
   Age and/or weight at dosing: young adult; males: 175-219 g, females: 141-172 g
   Source: Ace Animals, Inc., Boyertown, PA
   Acclimation period: 6, 8, or 9 days
   Diet: Purina Rodent Chow No. 5012
   Water: filtered tap water, *ad libitum*
   Housing: individually in suspended stainless steel cages with mesh floors
   Environmental conditions:
   Temperature: 16-26°C
   Humidity: not reported
   Air changes: not reported
   Photoperiod: 12 hour light/dark

### B. STUDY DESIGN AND METHODS

1. In life dates

   Start: February 4, 17, or 22, 1999; end: March 8, 1999

2. Animal assignment and treatment

Following an overnight fast, groups of five rats/sex were given a single 2000, 2700, or 3500 mg/kg dose of the test material by gavage. The animals were observed for clinical signs of toxicity and mortality at least once daily for 14 days. They were weighed on study days 0, 7, and 14. All rats were necropsied.

**TABLE 1. Doses, mortality/animals treated**

| Dose (mg/kg) | Males | Females | Combined |
|---|---|---|---|
| 2000 | 1/5 | 1/5 | 2/10 |
| 2700 | 3/5 | 2/5 | 5/10 |
| 3500 | 3/5 | 5/5 | 8/10 |

Data taken from Table 1, p. 11, MRID 44924405.

3. Statistics

Calculation of the oral $LD_{50}$ was by using Probit Analysis by the method of Finney.

## II. RESULTS AND DISCUSSION

### A. MORTALITY

Mortality is given in Table 1. Three high-dose females died on the day of dosing. One mid-dose male died on day 1. One low-dose female, one mid-dose female, and three males and two females in the high-dose group died on day 2. One low-dose male and one mid-dose female died on day 3. Two mid-dose males died on day 5.

The oral $LD_{50}$s for males, females, and combined were 2801 mg/kg, 2572 mg/kg, and 2667 mg/kg (95% C.L. 2086-3390 mg/kg), respectively. This places ACLD-128 in TOXICITY CATEGORY III.

### B. CLINICAL OBSERVATIONS

Hunched posture, anogenital staining, hypoactivity, diarrhea, reduced fecal volume, soft feces, and/or distended abdomens were noted from all rats. The survivors recovered by day 7. Some of the decedents had irregular respiration and gasping, were cold to touch, and/or exhibited prone posture prior to death.

### C. BODY WEIGHT

All surviving rats had normal body weight gains.

D. NECROPSY

Moderately red lungs, red/yellow/black intestines, distended/fluid filled/moderately red stomachs, discolored livers, and gaseous distended gastrointestinal tracts were noted from the decedents. No gross abnormalities were noted from the survivors.

E. DEFICIENCIES

The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION REPORT

**ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE**
(ACLD-128)

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT (81-2)
MRID 44924406

Prepared for

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K129

Primary Reviewer:
Susan Chang, M.S.
Signature: S Chang
Date: NOV 1 3 1999

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.
Signature: H T Borges
Date: NOV 1 3 1999

Robert H. Ross, M.S., Group Leader
Signature: Robert H. Ross
Date: NOV 1 3 1999

Quality Assurance:
LeeAnn Wilson, M.A.
Signature: L. A. Wilson
Date: NOV 1 3 1999

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Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

EPA Reviewer: Wallace Powell, ~~Ph.D.~~ _____, Date _____

EPA Work Assignment Manager: Nader Elkassabany, Ph.D. _____, Date _____

## DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rat
OPPTS 870.1200 [§81-2]

DP BARCODE: D259873
P.C. CODE: 069105

SUBMISSION CODE: S569138
CASE NO.: 066315

TEST MATERIAL (PURITY): ACLD-128 (10.31% Quat, a.i.)

SYNONYMS: not reported

CITATION: Moore, G.E. (1999) Acute dermal toxicity study in rats - Limit test. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project identification number 7132, April 7, 1999. MRID 44924406. Unpublished.

SPONSOR: Albemarle® Corporation, Health & Environment, 451 Florida Street, Baton Rouge, LA 70801-1765

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 44924406) approximately 10% of the body surface area of five male and five female young adult Sprague-Dawley rats was dermally exposed to 2000 mg/kg (Limit Test) ACLD-128 (10.31% Quat, a.i., Lot No. 8504-117) for 24 hours. The animals were observed for 14 days.

None of the animals died during the study. One male had anogenital staining on day 1 with recovery by day 2. Blanching and eschar was noted on the dose site of all rats. All rats had normal body weight gains during the study. No gross abnormalities were noted at necropsy.

**The dermal $LD_{50}$ for males, females, and combined was > 2000 mg/kg (Limit Test).**

**ACLD-128 is in TOXICITY CATEGORY III based on the $LD_{50}$.**

This acute dermal study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute dermal study (81-2)in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

# I. MATERIALS AND METHODS

## A. MATERIALS

### 1. Test material: ACLD-128

Description: blue liquid
Lot/Batch #: 8504-117
Composition: 10.31% Quat

### 2. Vehicle and/or positive control

None

### 3. Test animals

Species: rat
Strain: Sprague-Dawley derived
Age and/or weight at dosing: young adult; males: 214-258 g, females: 193-213 g
Source: Ace Animals, Inc., Boyertown, PA
Acclimation period: 13 days
Diet: Purina Rodent Chow No. 5012
Water: filtered tap water, *ad libitum*
Housing: individually in suspended stainless steel cages with mesh floors
Environmental conditions:
Temperature: 20-22°C
Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark

## B. STUDY DESIGN AND METHODS

### 1. In life dates

Start: February 1, 1999; end: February 15, 1999

### 2. Animal assignment and treatment

The study was conducted as a limit test using five male and five female rats. Animals were given a single 2000 mg/kg dose of ACLD-128 applied to a 2x3 inch clipped area (approximately 10% of the body surface). The application site was covered with a gauze pad and wrapped with tape. The covering was removed 24 hours later and the site wiped with water and a towel. The animals were observed for clinical signs of toxicity between one and three hours after treatment and at least daily thereafter for

14 days. They were weighed prior to test material application, and on study days 7 and 14. All rats were sacrificed and necropsied.

3. Statistics

Calculation of the dermal $LD_{50}$ was not required.

## II. RESULTS AND DISCUSSION

### A. MORTALITY

None of the rats died during the study.

The dermal $LD_{50}$ for males, females, and combined was > 2000 mg/kg. This places ACLD-128 in TOXICITY CATEGORY III.

### B. CLINICAL OBSERVATIONS

One male had anogenital staining on day 1 with recovery by day 2. Blanching and eschar was noted at the dose site of all rats.

### C. BODY WEIGHT

All animals had normal body weight gains.

### D. NECROPSY

No gross abnormalities were noted.

### E. DEFICIENCIES

The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION REPORT

**ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE**
(ACLD-128)

STUDY TYPE: ACUTE INHALATION TOXICITY - RAT (81-3)
MRID 44924407

Prepared for

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K129

Primary Reviewer:
Susan Chang, M.S.

Signature: Susan Chang
Date: NOV 13 1999

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H T Borges
Date: NOV 13 1999

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: NOV 13 1999

Quality Assurance:
LeeAnn Wilson, M.A.

Signature: L. A. Wilson
Date: NOV 13 1999

Disclaimer

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Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

EPA Reviewer: Wallace Powell, ~~Ph.D.~~ _____, Date _____

EPA Work Assignment Manager: Nader Elkassabany, Ph.D. _____, Date _____

## DATA EVALUATION RECORD

STUDY TYPE: Acute Inhalation Toxicity - Rat
OPPTS 870.1300 [§81-3]

DP BARCODE: D259873 SUBMISSION CODE: S569138
P.C. CODE: 069105 CASE NO.: 066315

TEST MATERIAL (PURITY): ACLD-128 (10.31% Quat, a.i.)

SYNONYMS: not reported

CITATION: Wnorowski, G. (1999) Acute inhalation toxicity study in rats. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project identification number 7133, April 6, 1999. MRID 44924407. Unpublished.

SPONSOR: Albemarle® Corporation, Health & Environment, 451 Florida Street, Baton Rouge, LA 70801-1765

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 44924407), groups of five male and five female young adult Sprague-Dawley derived rats were exposed whole body to ACLD-128 (10.31% Quat, a.i., Lot No. 8504-117) for 4 hours and 15 minutes at a concentration of 0.052 or 0.51 mg/L. The mass median aerodynamic diameters were estimated to be 2.3-2.9 $\mu$m and the geometric standard deviations were 1.68-1.75 $\mu$m. Approximately 60-76% of particles had an aerodynamic diameter $\leq$3.3 $\mu$m. The animals were observed for 14 days.

No rats in the low-dose group died during the study. Eight high-dose rats died during exposure and two high-dose rats died within 15 hours of exposure. Hunched posture, hypoactivity, irregular respiration, and/or dyspnea were noted from all low-dose rats. The rats recovered by day 13 or earlier. In addition, reduced fecal volume was noted from two females in the low-dose group. One male and one female in the high-dose group had irregular respirations, dyspnea, gasping, rales, hunched or prone postures, hypoactivity, and/or red nasal discharges prior to death. With the exception of one male and two females that lost weight during the first week, all surviving rats had normal body weight gains. All decedents had dark, mottled red, extremely edematous lungs. In addition, one female decedent had a discolored liver and one female had slightly red intestines. Two surviving low-dose females had tan, slight gaseous distended intestines. No gross abnormalities were noted from the other survivors.

**The $LC_{50}$ for males, females, and combined was > 0.052 mg/L and < 0.51 mg/L.**

**ACLD-128 is in TOXICITY CATEGORY II based on the $LC_{50}$.**

This acute inhalation study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute inhalation study (81-3) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## I. MATERIALS AND METHODS

### A. MATERIALS

1. Test material: ACLD-128

   Description: blue liquid
   Lot/Batch #: 8504-117
   Composition: 10.31% Quat

2. Vehicle and/or positive control

   None

3. Test animals

   Species: rat
   Strain: Sprague-Dawley derived
   Age and weight at dosing: young adult; males: 199-239 g, females: 179-214 g
   Source: Ace Animals, Inc., Boyertown, PA
   Acclimation period: 7 or 9 days
   Diet: Purina Rodent Chow No. 5012
   Water: filtered tap water, *ad libitum*
   Housing: individually in suspended stainless steel cages with mesh floors
   Environmental conditions:
   Temperature: 17-24°C
   Humidity: not reported
   Air changes: not reported
   Photoperiod: 12 hour light/dark

### B. STUDY DESIGN AND METHODS

1. In life dates

   Start: February 16, 1999; end: March 4, 1999

2. Exposure conditions

Temperature and humidity were recorded every 15 minutes for the first hour of exposure and every 30 minutes thereafter for the remainder of the 4 hour and 15 minute exposure.

3. Animal assignment and treatment

Animals were assigned to the test groups noted in Table 1. Rats were exposed to ACLD-128 by whole body exposure for four hours and 15 minutes. They were observed at least every 30 minutes during exposure, upon removal from chamber, and at least once daily thereafter for 14 days. They were weighed prior to test material exposure and on days 7 and 14. All rats were necropsied.

**TABLE 1. Concentrations, exposure conditions, mortality/animals treated**

| Nominal Conc. (mg/L) | Grav. Conc. (mg/L) | MMAD ($\mu$m) | GSD ($\mu$m) | Particles $\leq$3.3 $\mu$m (%) | Temp. (°C) | Humidity (%) | Male | Female | Combined |
|---|---|---|---|---|---|---|---|---|---|
| 1.22 | 0.052 | 2.3-2.4 | 1.73-1.75 | 70-76 | 22 | 41-52 | 0/5 | 0/5 | 0/10 |
| 11.03 | 0.51 | 2.9 | 1.68-1.72 | 60 | 21 | 43-88 | 5/5 | 5/5 | 10/10 |

Data were taken from pp. 16 and 18-22 and 4 and 6-8, MRID 44924407.

4. Generation of the test atmosphere and description of the chamber

The exposure atmosphere was generated using a 1/4 inch JCO atomizer, FC4 fluid cap and AC1502 air cap (Spraying Systems Inc.). The test material was metered to the atomization nozzle through Tygon tubing using a pump. Filtered air was supplied by an air compressor or compressed dry air connected to the spray atomization nozzle. Additional diluent air was supplied directly to the exposure chamber from filtered conditioned ambient source. The average total airflow was 45.6 liters/min and the whole body exposure chamber volume was 150 L.

Time to equilibrium was approximately 15 min.

Analytical chemistry - None

**Test atmosphere concentration** - Gravimetric samples were collected using glass fiber filters six times from the breathing zone of the animals during exposure. Filter papers were weighed before and after collection to determine the mass collected. The

value was divided by the total volume of air sampled to determine the chamber concentration. The average results are in Table 1 above.

**Particle size determination** - Particle size of each exposure concentration was determined using an eight-stage Andersen cascade impactor. The test material concentration collected by each stage was determined gravimetrically. The aerodynamic mass median diameter and geometric standard deviation were determined graphically using two-cycle logarithmic probit axes. Results are in Table 1 above.

5. Statistics

Calculation of the inhalation $LC_{50}$ was not required.

## II. RESULTS AND DISCUSSION

### A. MORTALITY

No rats in the low-dose group died during the study. Eight high-dose rats died during exposure and two high-dose rats died within 15 hours of exposure.

The $LC_{50}$ for males, females, and combined was > 0.052 mg/L and < 0.51 mg/L. This places ACLD-128 in TOXICITY CATEGORY II.

### B. CLINICAL OBSERVATIONS

Hunched posture, hypoactivity, irregular respirations, and/or dyspnea were noted from all low-dose rats. The rats recovered by day 13 or earlier. In addition, reduced fecal volume was noted from two females in the low-dose group. One male and one female in the high-dose group had irregular respirations, dyspnea, prone posture, gasping, rales, hunched posture, hypoactivity, and/or red nasal discharges prior to death.

### C. BODY WEIGHT

With the exception of one male and two females that lost weight during the first week, all surviving rats had normal body weight gains.

### D. NECROPSY

All decedents had dark, mottled red, extremely edematous lungs. In addition, one female decedent had a discolored liver and one female had slightly red intestines. Two surviving low-dose females had tan, slight gaseous distended intestines. No gross abnormalities were noted from the other survivors.

E. DEFICIENCIES

The humidity and air change frequency of the animal rooms were not reported. These would not affect the study results.

DATA EVALUATION REPORT

**ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE**
(ACLD-128)

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (81-5)
MRID 44924408

Prepared for

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K129

Primary Reviewer:
Susan Chang, M.S.

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Secondary Reviewers:
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Signature: H.T Borges
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Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: NOV 1 3 1999

Quality Assurance:
LeeAnn Wilson, M.A.

Signature: L. A. Wilson
Date: NOV 1 3 1999

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Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

EPA Reviewer: Wallace Powell, Ph.D. _____, Date _____

EPA Work Assignment Manager: Nader Elkassabany, Ph.D. _____, Date _____

## DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit
OPPTS 870.2500 [§81-5]

DP BARCODE: D259873 SUBMISSION CODE: S569138
P.C. CODE: 069105 CASE NO.: 066315

TEST MATERIAL (PURITY): ACLD-128 (10.31% Quat, a.i.)

SYNONYMS: not reported

CITATION: Moore, G.E. (1999) Primary dermal irritation study in rabbits. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project identification number 7135, April 7, 1999. MRID 44924408. Unpublished.

SPONSOR: Albemarle® Corporation, Health & Environment, 451 Florida Street, Baton Rouge, LA 70801-1765

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 44924408) one male and two female adult New Zealand white rabbits were dermally exposed to 0.5 mL ACLD-128 (10.31% Quat, a.i., Lot No. 8504-117) for 4 hours on the dorsal trunk. The animals were observed for 10 days. Irritation was scored by the method of Draize.

Very slight and well defined erythema were noted on 1/3 and 2/3 rabbits, respectively, one hour following patch removal. By 24 hours, well defined to moderate erythema was noted on all rabbits that intensified to severe by 72 hours and persisted through the end of the study. Moderate to severe edema was noted on all rabbits one hour after patch removal that persisted through day 7. By the end of the study, slight to moderate edema was noted on all rabbits. Eschar was present on all rabbits by 72 hours that persisted through the end of the study.

**In this study, ACLD-128 was corrosive and is in TOXICITY CATEGORY I for primary dermal irritation.**

This study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for a primary dermal irritation study (81-5) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

# I. MATERIALS AND METHODS

## A. MATERIALS

### 1. Test material: ACLD-128

Description: blue liquid
Lot/Batch #: 8504-117
Composition: 10.31% Quat

### 2. Vehicle

None

### 3. Test animals

Species: rabbit
Strain: New Zealand white
Age and weight at dosing: adult; weight of males and females not reported
Source: Davidson's Mill Farm, South Brunswick, NJ
Acclimation period: 13 days
Diet: pelleted Purina Rabbit Chow No. 5326
Water: filtered tap water, *ad libitum*
Housing: individually in suspended stainless steel cages with mesh floors
Environmental conditions:
Temperature: 20-22°C
Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark

## B. STUDY DESIGN AND METHODS

### 1. In life dates

Start: February 2, 1999; end: February 12, 1999

### 2. Animal assignment and treatment

One male and two female animals were given a single 0.5 mL dose of ACLD-128 applied to a 6 $cm^2$ clipped intact site on the dorsal trunk. The application sites were covered with gauze and wrapped with semi-occlusive tape. Elizabethan collars were placed on the rabbits. The dressings were left in place for 4 hours, after which they were removed and the application sites wiped with water and a towel. The sites were scored for erythema and edema according to the Draize method 1, 24, 48, and 72 hours, and 7 and 10 days after patch removal.

## II. RESULTS AND DISCUSSION

A. Very slight erythema and well defined erythema were noted on 1/3 and 2/3 rabbits, respectively, one hour following patch removal. By 24 hours, well defined to moderate erythema was noted on all rabbits that intensified to severe by 72 hours and persisted through the end of the study. Moderate to severe edema was noted on all rabbits one hour after patch removal that persisted through day 7. By the end of the study, slight to moderate edema was noted on all rabbits. Eschar was present on all rabbits by 72 hours that persisted through the end of the study.

ACLD-128 was corrosive and is in TOXICITY CATEGORY I.

B. DEFICIENCIES

The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

# DATA EVALUATION REPORT

**ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE**
(ACLD-128)

STUDY TYPE: DERMAL SENSITIZATION - GUINEA PIG (81-6)
MRID 44924409

Prepared for

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
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Action No. K129

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Quality Assurance:
LeeAnn Wilson, M.A.

Signature: L. A. Wilson
Date: NOV 1 3 1999

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

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Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

EPA Reviewer: Wallace Powell, Ph.D. _____, Date _____

EPA Work Assignment Manager: Nader Elkassabany, Ph.D. _____, Date _____

## DATA EVALUATION RECORD

STUDY TYPE: Dermal Sensitization - Guinea Pig
OPPTS 870.2600 [§81-6]

DP BARCODE: D259873 SUBMISSION CODE: S569138
P.C. CODE: 069105 CASE NO.: 066315

TEST MATERIAL (PURITY): ACLD-128 (10.31% Quat, a.i.)

SYNONYMS: not reported

CITATION: Wnorowski, G. (1999) Dermal sensitization test (Buehler method). Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project identification number 7136, April 7, 1999. MRID 44924409. Unpublished.

SPONSOR: Albemarle® Corporation, Health & Environment, 451 Florida Street, Baton Rouge, LA 70801-1765

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 44924409) with ACLD-128 (10.31% Quat, a.i., Lot No. 8504-117), 30 young adult male Hartley guinea pigs were tested using the Buehler method.

Very faint to moderate erythema was noted on all animals 24 and 48 hours after the first induction. No to faint usually confluent erythema was noted on all animals 24 and 48 hours after the second induction. No to very faint usually nonconfluent erythema was noted on all animals 24 and 48 hours after the third induction. Following challenge, dermal irritation suggestive of sensitization was not observed on the test or naive control animals after challenge. The study report included a DNCB positive control study which was carried out within six months of the current study. The results were appropriate.

**In this study, ACLD-128 was not a dermal sensitizer.**

This study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for a dermal sensitization study (81-6) in the guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

# I. MATERIALS AND METHODS

## A. MATERIALS

### 1. Test material: ACLD-128

Description: blue liquid
Lot/Batch #: 8504-117
Composition: 10.31% Quat

### 2. Vehicle and positive control

Vehicle: distilled water; positive control: 1-Chloro-2,4-dinitrobenzene (DNCB) (historical data)

### 3. Test animals

Species: guinea pig
Strain: Hartley
Age and weight at start of treatment: young adult; males: 349-400 g
Source: Davidson's Mill Farm, South Brunswick, NJ
Acclimation period: 6 days
Diet: pelleted Purina Guinea Pig Chow No. 5025
Water: filtered tap water, *ad libitum*
Housing: individually in suspended stainless steel cages with mesh floors
Environmental conditions:
Temperature: 18-23 °C
Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark

## B. STUDY DESIGN AND METHODS

### 1. In life dates

Start: January 27, 1999; end: February 25, 1999

### 2. Animal assignment and treatment

The animals were induced and challenged according to the method of Buehler. The dorsal area and flanks of 30 male guinea pigs were clipped. For the induction phase, 0.4 mL of test material in distilled water was applied with an occlusive 25 mm Hilltop Chamber for six hours once each week for three weeks to the dorsal flank of 20 test animals. The test material was 6%, 6%, and 4% in distilled water for the first, second, and third induction, respectively. Twelve days after the last induction dose, the animals were challenged with 0.4 mL of 2% test material in distilled water under

occlusion to naive sites for 6 hours. A naive control group (10 animals) was treated with 0.4 mL of 2% test material in distilled water at challenge only. Reactions were scored 24 and 48 hours post exposure.

## II. RESULTS AND DISCUSSION

### A. INDUCTION REACTIONS AND DURATION

Very faint usually nonconfluent erythema (score = 0.5), faint usually confluent erythema, and moderate erythema were noted on 8/20, 11/20, and 1/20 animals, respectively, 24 hours after the first induction. Very faint usually nonconfluent erythema, faint usually confluent erythema, and moderate erythema were noted on 9/20, 9/20, and 2/20 animals, respectively, 48 hours after the first induction. No to faint usually confluent erythema was noted on all animals 24 and 48 hours after the second induction. No to very faint usually nonconfluent erythema was noted on all animals 24 and 48 hours after the third induction.

### B. CHALLENGE REACTIONS AND DURATION

Very faint usually nonconfluent erythema was noted on 7/20 test animals 24 hours following challenge with resolution on 3/20 animals by 48 hours. Very faint usually nonconfluent erythema was noted on 4/10 naive control animals 24 hours following challenge with resolution on 1/10 animals by 48 hours.

ACLD-128 was not a dermal sensitizer.

### C. POSITIVE CONTROL

The study report include a DNCB positive control study which was carried out within six months of the current study. The results were appropriate.

### D. ADDITIONAL TESTING

It is the reviewer's opinion that the study was conducted in a manner suitable to detect the sensitization potential of the test material. No additional testing is needed.

### E. DEFICIENCIES

On page 21 in the study report, the table was misidentified as challenge phase skin reaction scores (test substance). This table should be the naive control skin reaction scores after challenge. The humidity and air change frequency of the animal room were not reported. These would not affect the study results.